



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
1401 Rockville Pike  
Rockville MD 20852-1448

Reference Numbers: 95-1530, 95-1531 and 95-1532

Ms. Brigitte W. Knudsen  
Statens Seruminstitut  
5, Artillerivej  
DK-2300 Copenhagen S  
DENMARK

JUL 29 1998

Dear Ms. Knudsen:

This letter hereby issues Department of Health and Human Services Biologics License No. 1255 to Statens Seruminstitut, Copenhagen, Denmark, in accordance with the provisions of Section 351(a) of the Public Health Service Act as amended November 21, 1997 (FDAMA; Public Law 105-115), controlling the manufacture and sale of biological products. This license authorizes you to manufacture and import into this country to ship for sale, barter, or exchange those products for which your company has demonstrated compliance with establishment and product standards.

Under this license you are authorized to manufacture the products Tetanus Toxoid Concentrate (For Further Manufacturing Use) and Diphtheria Toxoid Concentrate (For Further Manufacturing Use) to be shipped to North American Vaccine, Inc., in a shared manufacturing arrangement for the manufacture of Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed (DTaP).

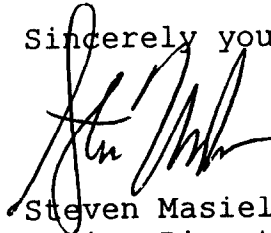
The dating period for these products will be 36 months from the date of manufacture. The date of manufacture is defined as the date the bulk purified toxoids are sterile filtered prior to final product release testing. Any requests to extend the dating period for these products beyond 36 months will require the submission of a Supplement to your license application with supporting data. Alternatively, you may submit a stability protocol for prior approval to be used for extension of dating as a Supplement to your license application.

Changes in the manufacturing, testing, packaging or labeling of your Diphtheria and Tetanus Toxoids Concentrates (For Further Manufacturing Use) or in the manufacturing facilities may require the submission of a Supplement to your license application for our review and written approval prior to implementation. Any such changes which may effect the safety, purity and potency of the products when used to prepare DTaP should also be reported simultaneously to North American Vaccine, Inc., the licensed manufacturer of the DTaP.

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It is requested that you acknowledge receipt of the enclosed  
Biologics License to the Director, Division of Vaccines and  
Related Products Applications, HFM-475.

Sincerely yours,



Steven Masiello  
Acting Director  
Office of Compliance  
and Biologics Quality  
Center for Biologics  
Evaluation and Research



M. Carolyn Hardegree, M.D.  
Director  
Office of Vaccines  
Research and Review  
Center for Biologics  
Evaluation and Research